patient privacy in research, it has significant limitations in practice. Too often individuals give consent when they do not fully understand the ramifications of what they have agreed to—and this is particularly true for individuals who are sick and vulnerable. CDT has written about the limits of consent in protecting privacy in health care (McGraw 2009b), as well as on the Internet (CDT 2009). In both articles, we caution against overreliance on the typical "notice and consent" framework for protecting privacy. We have instead called for a comprehensive framework of rules to protect information, so that consent cannot be used as a shield for inappropriate uses and disclosures of information.

The group harms discussed by Dr. Rothstein in his article would not be avoided by requiring individual consent. Because of the limits of consent, too many individuals would still knowingly agree to participate in research without a full appreciation of the potential adverse consequences, either for themselves or for their peer groups. We should not ask individuals to bear the burden of ensuring the proper conduct of health information research. Ultimately, we need a more effective paradigm for protecting privacy, as well as individual autonomy and dignity, while also advancing the conduct of research in the public interest. ■

REFERENCES

Center for Democracy & Technology. 2009. http://www.cdt.org/files/pdfs/20091105_ftc_priv_comments.pdf.

McGraw, D. 2009a. http://www.cdt.org/paper/encouraging-use-and-rethinking-protections-de-identified-and-anonymized-health-data

McGraw, D. 2009b. http://www.cdt.org/paper/rethinking-role-consent-protecting-health-information-privacy

Rothstein, M. A. 2010. Is deidentification sufficient to protect health privacy in research? *American Journal of Bioethics* 10(9): 3–11.

More Than One Binary

Nicolas P. Terry, Saint Louis University School of Law

Rothstein (2010) provides a carefully articulated critique of our current approach to the privacy of research data, particularly that sourced from electronic medical records (EMRs). The Common Rule and Health Insurance Portability and Accountability Act (HIPAA) privacy protection "holes," and hence the underprotection of personal health data, triggered by deidentification are well known. Rothstein's contribution here is to expose the gross oversimplification of the identification–deidentification binary. His article raises further questions about deidentification as an appropriate touchstone because of the processes and issues inherent in stripping identifying information from electronic medical records, calls out the unacceptability of having different deidentification matrixes for research and patient care, and speculates on the appropriate privacy protective models with which to supplement deidentification.

In some cases there are relatively obvious solutions to the issues he exposes. For example, if EMRs currently are deficient (or inconsistent) in their ability to export deidentified data, then the current regulatory models being readied for EMR certification (Office of the National Coordinator for Health Information Technology) or even the EMR meaningful use matrix (Centers for Medicare & Medicaid Services) should be harnesses to remedy this deficiency.

Other problem areas (and problematic they are) identified by Rothstein are not accompanied by any proposals. For example, his article offers no approach to the reidentification issue or solution to the deidentification paradox associated with unique data such as genetic information derived from biologics. It may be time to reframe these issues.

Another problem Rothstein identifies is the potential for group harm. Here he uses the example of the recently settled litigation between the Havasupai Native American tribe and Arizona State University (Capriccioso 2010). The solution apparently endorsed by Rothstein is to use an enhanced informed consent model. Yet it is one that would be so dependent on speculation by the researcher that in practice it would be useless, leading to the same kind of pro forma disclaimers Rothstein criticizes in the "Commercial Exploitation" section of his article. Consents to the indeterminate, like waivers of all rights, are insulting to our concept of autonomy and our goal of informed choice.

Such niggles aside, Rothstein's article forces us to examine anew some quite fundamental questions, questions hinted at by some of the opinion data cited in his article. Lawyers, bioethicists, and regulators (the same ones who draw the identification binary) have built a decision tree founded on discrete branches for patients and research subjects. From the perspective of the data steward that may make sense. But is it meaningful from the perspective of the patient-subject? Although the research subject likely enters the endeavor with more sense of altruism toward others

Address correspondence to Nicolas P. Terry, Chester A. Myers Professor of Law, Saint Louis University School of Law, 3700 Lindell Blvd., St Louis, MO 63108, USA. E-mail: terry@slu.edu

rather than personal healing, the two roles are unlikely to be fully dichotomized.

Let us take the Havasupai tribe incident as a container for this and other questions. Assume the plaintiffs' allegations to be true (the researcher involved has strenuously denied this; Capriccioso 2010), and that members of the tribe consented to give blood samples solely to accelerate research into the tribe's extremely high rate of diabetes. Suppose the research had provided the answer to that and, incidentally, led to a new pharmaceutical to effectively treat diabetes, a drug that had immense commercial value. Would the tribe have objected? Suppose one of the not-consented-to research areas such as schizophrenia had led to a treatment modality that increased mental health in the tribe. Physicians and researchers view the consents (treatment, research, and confidentiality) of their patient-subjects as a one-time, winner-take-all matter rooted in foresight, not hindsight; their patients and subjects may not feel so constrained.

Recently, one Havasupai tribal council member commented, "I'm not against scientific research ... I just want it to be done right. They used our blood for all these studies, people got degrees and grants, and they never asked our permission" (Harmon 2010). How should lawyers and bioethicists begin to unpack such a statement? Is this a cry for our existing consent models? Or for refined ones that require a far more detailed, sophisticated, and personalized dialog as required by informed consent? Or do we need to look elsewhere?

The surveys quoted by Rothstein suggest that traditional autonomy-based mechanisms such as consent or waiver (even improved versions of the same) are not highly regarded by data subjects. Rather, such subjects, in Rothstein's words, want to "control the use of their samples and information."

The conclusion to be drawn from this is not that we need to develop a more nuanced approach to the identification–deidentification binary accompanied by improved privacy processes. Rather, it suggests we must confront a public demand for legal regulation that satisfies their heightened interests in what comes of the public's EMR data or biologics (Terry 2010). There are several mechanisms that would bring increased control. Data or biologics used in research could be limited to those collected from anonymous sources; a regime of market inalienability (Radin 1987), prohibiting any commercial exploitation of data or biologics, could be imposed (Terry and Francis 2007); or we could impose some type of "trust" model that would channel profits or some percentage of profits from research to public funds or to the research group.

For the research industry (whether profit or nonprofit) such proposals no doubt are anathematic. But unless such proposals are put on the table it is hard to believe that we will have the discussions that we need to find the correct calibration between researcher and research subject/patient. It is highly likely that our fellow citizens are far more altruistic than we would believe. But until we involve them in discussion, find the point of accommodation, and regulate accordingly, we will continue along a tortuous and perhaps never-ending journey of process reform. ■

REFERENCES

Capriccioso, R. 2010. Havasupai blood case settled. *Indian Country Today*, April 21. Available at: http://www.indiancountrytoday.com/archive/91728874.html

Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs; Electronic Health Record Incentive Program. Available at: http://www.ofr.gov/OFRUpload/OFRData/2010-17207_PI.pdf (accessed July 13, 2010).

Harmon, A. 2010. Indian tribe wins fight to limit research of its DNA. New York Times, April 21. Available at: http://www.nytimes.com/2010/04/22/us/22dna.html?scp = 7&sq = havasupai&st = cse

Office of the National Coordinator for Health Information Technology, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology. Available at: http://www.ofr.gov/OFRUpload/OFRData/2010–17210_PI.pdf (accessed July 13, 2010).

Radin, M. J. 1987. Market-inalienability. *Harvard Law Review* 100: 1849–1853.

Rothstein, M. 2010. Is deidentification sufficient to protect health privacy in research? *American Journal of Bioethics* 10(9): 3–11.

Terry, N. P. 2010. Legal barriers to realizing the public good in clinical data. In *Institute of Medicine, Clinical data as the basic staple of health learning: Creating and protecting a public good*. Washington, DC: National Institutes of Health, in press.

Terry, N. P., and L. P. Francis. 2007. Ensuring the privacy and confidentiality of electronic health records. *University of Illinois Law Review* 681–735.